Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL QUALITY MEASURES CLEARINGHOUSE

General

Title

Cardiovascular implantable electronic device (CIED): infection rate following CIED device implantation, replacement, or revision.

Source(s)

Heart Rhythm Society (HRS). HRS-9: infection within 180 days of cardiac implantable electronic device (CIED) implantation, replacement, or revision. Washington (DC): Heart Rhythm Society (HRS); 2015 Dec 18. 11 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Outcome

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the infection rate following cardiovascular implantable electronic device (CIED) device implantation, replacement, or revision.

This measure is to be reported a minimum of once per reporting period for patients with a CIED device implantation, replacement, or revision performed from January 1, 2016 through June 30, 2016 of the reporting period. This measure may be reported by clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Infection rates for new implants shall be calculated and reported separately from device replacements and revisions.

There are two reporting criteria for this measure:

Patients, regardless of age, with a new CIED
Patients, regardless of age, with a replaced or revised CIED

Rationale

The rate of implantable cardioverter-defibrillator (ICD) infections has been increasing faster than that of device implantation and is associated with substantial morbidity, mortality, and financial cost. A recent study including over 200,000 ICD implant patients found 2 percent of patients undergoing ICD implantation experienced a device-related infection. Patients who developed an ICD infection were likely to have more comorbidity burden, warfarin use, and coronary sinus lead, device upgrade/malfunction as the last surgery, peri-ICD implant complications, and non-eligible professional (EP) trained operator. The evidence demonstrates the need to measure performance in this area.

In recognition that there is an absence of applicable physician-level performance measures for the profession of cardiac electrophysiology, the Heart Rhythm Society (the international professional society focused on the care of patients with heart rhythm disorders) convened a Performance Measures Development Task Force to consider and develop potential physician-level measures for cardiac electrophysiologists. The task force consisted of thought leaders in 1) implantation of cardiac implantable electronic devices (CIEDs) including pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization devices (pacemaker or ICD); and implantable loop recorders (ILRs), 2) cardiovascular health policy, 3) performance measures development, 4) clinical outcomes, and 5) population science. The process for consideration of the evidence included review of the relevant literature referenced within this document and in the knowledge of the members of the task force (Voigt, Shalaby, & Saba, 2006; Cabell et al., 2004; Voigt, Shalaby, & Saba, 2010; Greenspon et al., 2011; Sohail et al., 2011; Nery et al., 2010; Ferguson et al., 1996; Uslan et al., 2007; Lee et al., 2010; Klug et al., 2007; Alter et al., 2005; Al-Khatib et al., 2008; de Oliveira et al., 2009; Uslan et al., 2012; Borleffs et al., 2010; Sohail et al., 2007; Bloom et al., 2006; Baddour et al., 2010; Le et al., 2011; Johansen et al., 2011; Al-Khatib et al., 2005; Tarakji et al., 2010).

The number of CIED-related infections in the United States continues to increase out of proportion to the increase in the CIED implantation rates (Voigt, Shalaby, & Saba, 2006; Cabell et al., 2004; Voigt, Shalaby, & Saba, 2010). This infection burden is associated with increased mortality, prolonged hospital stays and high financial costs (Greenspon et al., 2011; Sohail et al., 2011; Ferguson et al., 1996). Collectively, the incidence of CIED infection has ranged from 0.3% to 2.9% across the literature evaluated (Greenspon et al., 2011; Sohail et al., 2011; Nery et al., 2010; Uslan et al., 2007; Lee et al., 2010; Klug et al., 2007; Alter et al., 2005; Al-Khatib et al., 2008; Uslan et al., 2012; Bloom et al., 2006; Baddour et al., 2010; Johansen et al., 2011). In the vast majority of patients, CIED infection is preventable, and an association between a higher volume of ICD implants and a lower rate of infections has been demonstrated (Tarakji et al., 2010). This is why a performance measure that could lower the risk of CIED infection is critically needed.

Evidence for Rationale

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Primary Health Components

Cardiovascular implantable electronic device (CIED) implantation, replacement, or revision; infection rate

Denominator Description

Reporting Criteria 1: All patients with a new cardiovascular implantable electronic device (CIED) from January 1 through June 30 of the reporting period

Reporting Criteria 2: All patients with replacement or revision of a CIED from January 1 through June 30 of the reporting period

See the related "Denominator Inclusions/Exclusions" field.

Numerator Description

Reporting Criteria 1: The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following cardiovascular implantable electronic device (CIED) implantation, replacement, or revision

Reporting Criteria 2: The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following CIED implantation, replacement, or revision

See the related "Numerator Inclusions/Exclusions" field.

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Unspecified

Extent of Measure Testing

Unspecified

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Hospital Inpatient

Hospital Outpatient

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Does not apply to this measure

Target Population Age

All patients, regardless of age

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Making Care Safer
Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Safety

Data Collection for the Measure

Case Finding Period

January 1 through June 30 of the reporting period

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Encounter

Institutionalization

Therapeutic Intervention

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions
Reporting Criteria 1: All patients with a new cardiovascular implantable electronic device (CIED) from January 1 through June 30 of the reporting period

Denominator Criteria (Eligible Cases) Reporting Criteria 1:

All patients, regardless of age

AND

Codes for CIED implantation, replacement, or revision (refer to the original measure documentation for International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM], International Classification of Diseases, Tenth Revision, Procedure Coding System [ICD-10-PCS] procedure codes)

AND/OR

Patient encounter during reporting period (refer to the original measure documentation for Current Procedural Terminology [CPT] codes)

AND

New CIED

AND NOT

Patients undergoing heart transplantation (refer to the original measure documentation for ICD-10-PCS procedure codes)

Reporting Criteria 2: All patients with replacement or revision of a CIED from January 1 through June 30 of the reporting period

Denominator Criteria (Eligible Cases) Reporting Criteria 2:

All patients, regardless of age

AND

Codes for CIED implantation, replacement, or revision (refer to the original measure documentation for ICD-10-CM, ICD-10-PCS procedure codes)

AND/OR

Patient encounter during reporting period (refer to the original measure documentation for CPT codes)

AND

Replaced or revised CIED

AND NOT

Patients undergoing heart transplantation (refer to the original measure documentation for ICD-10-PCS procedure codes)

Note:

CIEDs encompassed for this measure are the following devices:
- Pacemaker devices (single or dual chamber);
- Implantable cardioverter-defibrillators (ICDs, single or dual chamber);
- Cardiac resynchronization devices (pacemaker or ICD);
- Implantable loop recorders (ILRs)

Include only patients that have had CIED implantation, replacement, or revision performed by June 30. This timeframe allows for evaluation of infection requiring within 180 days within the reporting period. This will allow the evaluation of infection status post CIED implantation, replacement, or revision within the reporting year.

Exclusions
None

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions
Reporting Criteria 1: The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following cardiovascular implantable electronic device (CIED) implantation, replacement, or revision

Reporting Criteria 2: The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following CIED implantation, replacement, or revision

Note: Refer to the original measure documentation for administrative codes.

Exclusions
None

Numerator Search Strategy

Fixed time period or point in time

Data Source

Administrative clinical data

Registry data

Type of Health State

Adverse Health State

Instruments Used and/or Associated with the Measure

- 2016 Registry Individual Measure Flow: PQRS #393: HRS-9: Infection Within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision - Reporting Criteria One
- 2016 Registry Individual Measure Flow: PQRS #393: HRS-9: Infection Within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision - Reporting Criteria Two

Computation of the Measure

Measure Specifies Disaggregation

Measure is disaggregated into categories based on different definitions of the denominator and/or numerator

Basis for Disaggregation

There are two reporting criteria for this measure:

Reporting Criteria 1: Patients, regardless of age, with a new cardiovascular implantable electronic device (CIED)

> Denominator: All patients with a new CIED from January 1 through June 30 of the reporting period
> Numerator: The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following cardiovascular CIED implantation, replacement, or revision

Reporting Criteria 2: Patients, regardless of age, with a replaced or revised CIED

> Denominator: All patients with replacement or revision of a CIED from January 1 through June 30 of the reporting period
> Numerator: The number of patients from the denominator admitted with an infection requiring device removal or surgical revision within 180 days following CIED implantation, replacement, or revision

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a lower score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

HRS-9: infection within 180 days of cardiac implantable electronic device (CIED) implantation, replacement, or revision.

Submitter

Heart Rhythm Society - Disease Specific Society

Developer

Heart Rhythm Society - Disease Specific Society

Funding Source(s)

Unspecified

Composition of the Group that Developed the Measure

Unspecified

Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

Measure Initiative(s)

Physician Quality Reporting System

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2015 Dec

Measure Maintenance

Unspecified

Date of Next Anticipated Revision

Unspecified

Measure Status

This is the current release of the measure.

Measure Availability

Source not available electronically.

For more information, contact the Heart Rhythm Society (HRS) at 1325 G Street, NW, Suite 400, Washington, DC 20005; Phone: 202-464-3400; Fax: 202-464-3401; E-mail: info@HRSonline.org; Web site: www.hrsonline.org .

NQMC Status

This NQMC summary was completed by ECRI Institute on June 21, 2016. The information was verified by the measure developer on July 7, 2016.

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Production

Source(s)

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